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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/386,450 08/31/99 HOTTEN

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EXAMINER

HM12/0731
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ROOMED D	
ART UNIT	PAPER NUMBER

1647
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07/31/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/386,450

Applicant(s)

Hotten et al.

Examiner

David Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6, 7, 9-11, 13-18, and 20-25 is/are pending in the application.
- 4a) Of the above, claim(s) 2-4, 7, 10, 17, and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 9, 11, 13, 16, and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 2-4, 6, 7, 9-11, 13-18, and 20-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Not. to Comply, Raw Sq. List. Err. Rep.*

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DETAILED ACTION

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 13-27 have been renumbered 11-25.

2. The amendment filed 05/21/2001 (Paper No. 10) has been entered. Claims 2-4, 6, 7, 9, 10, 11, 13-18, 20-25 are pending. Claims 2-4, 7, 10, 17, 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6. Claims 6, 9, 11, 13, 16, 20-25 are being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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3. Claim 22 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read on a product of nature. It is suggested that the claims be limited to an isolated polypeptide.

4. Claims 6, 9 are rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "functional parts thereof" because it is unclear what function associated with what part is intended. The metes and bounds of the claim(s) are not clearly set forth. The rejection of record is applied to claims 13, 24. Applicants argue that claim 13 (claim 11) has been amended to recite "functional parts thereof". Applicants' arguments have been fully considered but they are not persuasive. The recitation of "functional parts thereof" in claim 6 lacks antecedent basis for the "functional parts thereof" in claim 13. Applicants argue that the specification at page 5 defines "functional parts". Applicants' arguments have been fully considered but they are not persuasive. The specification at page 5 rather than containing a limiting denotation of the term "functional parts", merely recites "for example" what a "functional part" may be. Although the specification identifies certain "functional parts" of MP52, limitations from the specification are not read into the claims.

5. Claim(s) 9, 13, 24 are rejected under 35 U.S.C. § 112, second paragraph, because they recite the term "auxiliary". Applicants argue that "auxiliary substances" are commonly known to

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those of skill in the pharmaceutical arts. Applicants' arguments have been fully considered but they are not persuasive because Applicants have offered no objective evidence of such knowledge or understanding. It is further noted that the dictionary defines "auxiliary" in the adjective sense as "Acting as a subsidiary; supplementary". It is unclear how the "auxiliary substance" subsidizes or supplements the TGF- β family member.

6. Claim(s) 6, 9, 11, 13, 16, 21 are rejected under 35 U.S.C. § 112, second paragraph, because they recite the term "mature". The rejection of record is applied to claims 23-25.

Applicants point to the specification at pages 4-5. Applicants' arguments have been fully considered but they are not persuasive. The specification at page 4 discloses that the start of the mature begins after nucleotide 1782. However, the specification does not disclose where after the nucleotide 1782 the mature protein begins. The specification at page 5 discloses that the region coding for the mature part of the protein extends from nucleotides 1783-2142. However, the specification does not disclose where within the sequence 1783-2142 the coding sequence for the mature protein begins and ends.

New formal matters, objections, and/or rejections:

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer

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readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached Raw Sequence Listing Error Report and Notice to Comply.

5 Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Applicant is requested to return a copy of the attached Raw Sequence Listing Error Report with the reply.

Claim Rejections - 35 USC § 112

8. The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which
10 applicant regards as the invention.

a. Claims 6, 9, 11, 13, 16, 23, 24, 25 are indefinite over the recitation of "mitogenic activity" because it is unclear what mitogenic activity is intended. The metes and bounds of the claim(s) are not clearly set forth.

b. A broad range or limitation together with a narrow range or limitation that falls
15 within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by

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"such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation "which encodes at least a functional part of the protein of the TGF- β family, wherein the functional part of maintains essentially the same osteo-inductive and/or mitogenic activity of the mature protein", and the claim also recites "which comprises the sequence shown in SEQ ID NO: 1" which is the narrower statement of the range/limitation. In the present instance, claim 11 recites the broad recitation "which encodes at least a functional part of the protein of the TGF- β family, wherein the functional part of maintains essentially the same osteo-inductive and/or mitogenic activity of the mature protein", and the claim also recites "which comprises a part of SEQ ID NO: 1 which encodes the mature protein" which is the narrower statement of the range/limitation. In the present instance, claim 11 recites the broad recitation "which encodes at least a functional part of the protein of the TGF- β family, wherein the functional part of maintains essentially the same osteo-inductive and/or mitogenic activity of the mature protein", and the claim also recites "which comprises a nucleotide sequence which encodes the amino acid sequence according to SEQ ID NO: 2" which is the narrower statement of the range/limitation. In the present instance, claim 11

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recites the broad recitation "which encodes at least a functional part of the protein of the TGF- β family, wherein the functional part of maintains essentially the same osteo-inductive and/or mitogenic activity of the mature protein", and the claim also recites "which comprises a nucleotide sequence which encodes a portion of the amino acid sequence according to SEQ ID NO: 2
5 wherein said portion is the mature protein" which is the narrower statement of the range/limitation.

c. Claim 20 depends from a canceled claim (claim 19), and thus makes no sense, since it is incomplete. The metes and bounds of the claim(s) are not clearly set forth.

d. Claim 21 is indefinite over the recitation of "signal peptide or propeptide parts"
10 because it is unclear if "parts" as in some portion of the signal peptide or propeptide, or "parts" as in an amalgam of discontinuous parts of the signal peptide or propeptide are intended, or if the signal peptide or the propeptide is intended. The metes and bounds of the claim(s) are not clearly set forth.

9. Claims 6, 9, 11, 13, 16, 23, 24, 25 are rejected under 35 U.S.C. 112, first paragraph, as
15 containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13, and the claims dependent thereon, are directed to or encompass an isolated protein of the TGF- β family encoded by an isolated

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nucleic acid molecule which comprises a nucleotide sequence which encodes a portion of the amino acid sequence according to SEQ ID NO: 2 wherein said portion is the signal or propeptide part. The only structural limitations to the protein are the signal or propeptide part of SEQ ID NO: 2. There are no structural or functional limitations to the mature, active portion of the TGF-
5 β family member protein. This is a genus claim. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus of mature, active portions of the TGF- β family member protein. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the
10 genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a TGF- β family member
15 encoded by an isolated nucleic acid molecule which comprises a nucleotide sequence which encodes a portion of the amino acid sequence according to SEQ ID NO: 2 wherein said portion is the signal or propeptide part, wherein the only structural limitations to the protein are the signal or propeptide part of SEQ ID NO: 2, alone is insufficient to describe the genus. One of skill in

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the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Alternatively, and/or in addition to the rejection above, support for the limitation wherein a TGF- β family member protein is encoded by an isolated nucleic acid molecule which comprises a nucleotide sequence which encodes a portion of the amino acid sequence according to SEQ ID NO: 2 wherein said portion is the signal or propeptide part, wherein the only structural limitations to the protein are the signal or propeptide part of SEQ ID NO: 2, and wherein there are no structural or functional limitations to the mature, active portion of the TGF- β family member protein, cannot be found in the specification as originally filed and the introduction of such a limitation raises the issue of new matter.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


5 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

10 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

15 
DAVID ROMEO
PRIMARY EXAMINER
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JULY 28, 2001